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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/800,855 03/07/01 SONIS

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023579 HM12/0620  
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EXAMINER

DEACROIX MIIRMET, C

ART UNIT

PAPER NUMBER

1614

DATE MAILED:

06/20/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/800,855**

Applicant(s)  
**SONIS et al.**

Examiner  
**Cybille Delacroix-Muirheid**

Art Unit  
**1614**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-34 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

### DETAILED ACTION

Due to the complex nature of the claims, a request for an oral election to the following election of species is not being made. Please see MPEP 812.01.

#### ***Supplemental Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-27, drawn to a method for inhibiting, preventing or treating mucositis, classified in class 514, subclass 21+.

*unit  
transverse*

II. Claims 28-34, drawn to a composition for treating oral mucositis, classified in class 424, subclass 464.

*-be cancelled*

2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for treating or preventing mucositis can be practiced with a materially different product such as sucralfate or chlorhexidine gluconate.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

4. This application contains claims directed to the following patentably distinct species of the claimed invention: **In Group I**, claim 1, a method of inhibiting, treating or preventing mucositis comprising administering to a human patient in need thereof (1) a first therapeutic agent comprising an NSAID, an inflammatory cytokine inhibitor or a mast cell inhibitor and (2) a second therapeutic agent comprising an MMP inhibitor, an NO inhibitor, an NSAID, an inflammatory cytokine inhibitor, **r** a mast cell inhibitor. In claim 15, a method of inhibiting, treating or preventing mucositis comprising administering to a human

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patient in need thereof a composition selected from the group consisting of an MMP inhibitor, an inflammatory cytokine inhibitor and a mast cell inhibitor (degranulation inhibitor, antihistamine or serine protease inhibitor, see claims 16-18).

**In Group II**, claim 28, a pharmaceutical composition for treating mucositis comprising (1) a first therapeutic agent comprising an NSAID, an inflammatory cytokine inhibitor or a mast cell inhibitor and (2) a second therapeutic agent comprising an MMP inhibitor, an NO inhibitor, an NSAID, an inflammatory cytokine inhibitor, **or** a mast cell inhibitor.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for the first and second therapeutic agents, above, as they relate to claim 1; a single disclosed species for the therapeutic agents above as they relate to claim 15; or for the first and second therapeutic agents, as they relate to claim 28 for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Please note that if a mast cell inhibitor is elected then Applicant must also further elect a species of mast cell inhibitor listed in claim 11, 16-18. If the inflammatory cytokine inhibitor is elected, then a further election of a species of inflammatory cytokine inhibitor listed in claims 4, 5, 10 is required. Finally, if the NSAID is elected, then a further election of species of NSAID listed in claims 2, 3. Currently, claims 1, 15 and 28 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.


Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cybille Delacroix-Muirheid whose telephone number is (703) 306-3227. The examiner can normally be reached on Tue-Fri from 8:30 to 6:00. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

CDM   
June 18, 2001

  
Cybille Delacroix-Muirheid  
Patent Examiner Group 1600